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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/614,853	07/08/2003	Henry Chiu	P1973R1	5148

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EXAMINER	
SPECTOR, LORRAINE	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 06/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/614,853	CHIU ET AL.	
	Examiner	Art Unit	
	Lorraine Spector, Ph.D.	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-30 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-30 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The claims are not in compliance with 37 C.F.R. §1. 126; there are no claims numbered 11, 29 or 30. The claims have been renumbered accordingly. Claims 1-30 are pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-9, 11 and 12, drawn to nucleic acids, vectors, host cells, expression of protein and fusion protiens, classified in class 435, subclass 69.7 for example.

II. Claims 10 and 15-18, drawn to protein, classified in class 530, subclass 350.

III. Claims 13-18, drawn to antibodies, classified in class 530, subclass 387.9.

IV. Claims 15-18, as drawn to antagonists, classification dependent upon species.

V. Claims 19-20 and 28, as drawn to a method of treatment using protein or agonist, classified in class 514, subclass 2.

VI. Claims 19-20, as drawn to a method of treatment using an antagonist, classification dependent upon species.

VII. Claims 19-20, as drawn to a method of treatment using an antibody, classified in class 424, subclass 130.1.

VIII. Claims 21 and 23, drawn to assaying protein using an antibody, classified in class 435, subclass 7.1.

IX. Claims 22, 29 and 30, drawn to a diagnostic assay in which gene expression is detected, classified in class 435, subclass 6.

X. Claims 24 and 27, drawn to an assay using cells that respond to PRO polypeptides, classified in class 435, subclass 7.21.

XI. Claims 25 and 26, drawn to an assay using cells that express PRO polypeptides, classified in class 435, subclass 7.21.

The inventions are distinct, each from the other because of the following reasons:

The polypeptide of Invention II is related to the nucleic acids of Invention I by virtue of encoding same. The DNA molecule has utility for the recombinant production of the protein in a host cell. Although the DNA molecules and proteins are related since the DNA encodes the

specifically claimed protein, they are distinct inventions because they are physically and functionally distinct chemical entities, and the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the DNA may be used for processes other than the production of the protein, such as nucleic acid hybridization assay.

The nucleic acid of Invention I is distinct from and unrelated to the antibody of Invention III because they are physically and functionally distinct chemical entities which share neither structure nor function. Also, neither is required for the manufacture of the other. The method of Invention I is distinct from and unrelated to the antibody of Invention III because the antibody may be neither made by nor used in the method.

Invention I is unrelated to each of inventions IV-XI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, none of the claimed methods makes use of the claimed nucleic acids or fusion protein, and the products of Inventions I and IV are distinct chemical entities with separate structures and functions. Accordingly, each of Inventions IV-XI requires a separate search from that required for Invention I, and such search would be burdensome, as the various areas of search are non-coextensive. Accordingly, restriction is proper.

The polypeptide of Invention II is related to the antibody of Invention III by virtue of being the cognate antigen, necessary for the production of the antibodies. Although the protein and antibody are related due to the necessary stearic complementarity of the two, they are distinct inventions because they are physically and functionally distinct chemical entities, and because the protein can be used another and materially different process from the use for production of the antibody, such as in a pharmaceutical composition in its own right, or in assays for the identification of agonists or antagonists of the protein.

The polypeptides of Invention II is unrelated to the antagonist of Invention IV, as the two compounds are mutually exclusive, have distinct structures, functions and modes of action, and are not disclosed as being capable of use together. Accordingly, restriction is proper.

Inventions II and each of Inventions V and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1)

the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the proteins may be used to make the antibodies of Invention III.

The products of Invention II are separate and distinct from each of the methods of Inventions VI-IX, as the products are neither made by nor used in the methods. Thus, separate searches are required, said searches presenting a burden to the examiner, and restriction is proper.

Inventions II and XI are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case although the products may be purified from the cells used in Invention XI, they may be made by substantively different cells (bacterial, e.g.) or chemically synthesized, or purified from their natural source. Accordingly, restriction is proper.

The antibodies of Invention III are related to the antagonists of Invention IV because some of the antibodies may also be antagonists. However, Invention III is not limited by function, and includes a large proportion of species that would not be antagonists, and Invention IV does not require an antibody. The searches for the two groups are not coextensive; a search for antibodies would not necessarily reveal antagonists, and vice versa. Accordingly, examination of both inventions would be burdensome, and restriction is proper.

Inventions III and each of Inventions V- VIII are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the antibody may be used in any of the distinct processes, or in substantively different processes, such as for protein purification. Accordingly, restriction is proper.

The antibodies of Invention III are separate and distinct from each of the methods of Inventions IX-XI, wherein the antibodies are neither made by nor required for the methods. Accordingly, restriction is proper.

The antagonists of Invention IV are separate and distinct from each of the methods of Inventions V and VII-XI, wherein the antagonists are neither made by nor required for the methods. Accordingly, restriction is proper.

Inventions IV and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the products may be used for imaging studies, or in vitro assays. Accordingly, restriction is proper.

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Groups V-XI are directed to methods that are distinct both physically and functionally, and are not required one for the other. Invention V requires administration of a PRO protein, which is not required by any of the other groups. Inventions VI-VIII involve administration of an antagonist which may be an antibody, or assaying protein using an antibody. Inventions V and VI use mutually exclusive active agents. Invention VII is related to each of inventions V and VI, but is distinct from each for reasons cited above in relationship to the products used. Invention VIII is separate and distinct from all the aforementioned methods, because different method steps are used to achieve different effect; said method steps require separate search and consideration, which would be burdensome. Invention IX requires an assay for gene expression, which is not required by any other groups, and uses different method steps to achieve different effect; said method steps require separate search and consideration, which would be burdensome. Finally, Inventions X and XI are cellular assays; cells are not required by the other methods, and the cellular assays require different method steps and starting materials than the other methods. Further, Inventions X and XI use non-overlapping types of cells; the former requiring cells that *respond* to PRO polypeptides, e.g. have receptors therefore, and the

latter requiring cells that *express* PRO polypeptides. Accordingly, separate and burdensome searches are required. Therefore, a search and examination of all seven methods in one patent application would result in an undue burden, since the searches for the seven methods are not co-extensive, the classification is different, and the subject matter is divergent.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Regardless of which of the above inventions is elected, further restriction is required under 35 U.S.C. 121:

A. One specific PRO sequence with SEQ ID NO:, i.e. select one nucleic acid or protein, as appropriate, from of SEQ ID NO: 1-28.

The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons. Each of SEQ ID NOs is a unique and separately patentable sequence, requiring a unique search of the prior art. Searching all of the sequences in a single patent application would constitute an undue search burden on the examiner and the USPTO's resources because of the non-coextensive nature of these searches.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

In order to be fully responsive, Applicant must elect one from Groups I - XI, and one from Group A to be examined even though the requirement is traversed. Applicant is advised that neither I - XI nor A are species election requirements; rather, each of I - XI, and A is a restriction requirement.

Election of Species

Should applicant elect Invention V, VI or VII, a further election of species is required:

This application contains claims directed to the following patentably distinct species: SLE, X-linked infantile hypogammaglobulinemia, polysaccharide antigen unresponsiveness, selective IgA deficiency, selective IgM deficiency, selective deficiency of IgG subclasses, immunodeficiency with hyper Ig-M, transient hypogammaglobulinemia of infancy, Burkitt's lymphoma, Intermediate lymphoma, follicular lymphoma, type II hypersensitivity, glomerulonephritis, and ankylosing spondylitis. The species are independent or distinct because each medical condition has different cause, effect and etiology, and requires separate search and consideration of the art.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 19 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Advisory Information

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Lorraine M. Spector. Dr. Spector can normally be reached Monday through Friday, 9:00 A.M. to 3:00 P.M. at telephone number 571-272-0893.

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's supervisor, Ms. Brenda Brumback, at telephone number 571-272-0961.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Official papers filed by fax should be directed to **571-273-8300**. Faxed draft or informal communications with the examiner should be directed to ***571-273-0893.***

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lorraine Spector, Ph.D.
Primary Examiner